In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Reissued for Public Availability Date: September 20, 2023

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NADINE LYNN McLEE,	*	
,	*	No. 20-1283V
	*	
Petitioner,	*	Special Master Christian J. Moran
	*	•
V.	*	Filed: August 18, 2023
	*	
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
·	*	
Respondent.	*	
* * * * * * * * * * * * * * * * * * * *	*	

<u>Nadine Lynn McLee</u>, *pro se*, Pittsburgh, PA, for petitioner; <u>Katherine C. Esposito</u>, United States Dep't of Justice, Washington, D.C., for respondent.

UNPUBLISHED DECISION DENYING COMPENSATION12

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

² Pursuant to Vaccine Rule 18(b), this Decision was initially filed on August 18, 2023, and the parties were afforded 14 days to propose redactions. The parties did not propose any redactions. Accordingly, this Decision is reissued in its original form for posting on the Court's website.

Nadine McLee alleged that the trivalent influenza ("flu") vaccine she received on September 27, 2017, caused her to suffer left shoulder injuries. Amended Pet., filed Mar. 3, 2021, at Preamble, ¶¶ 2-4. Ms. McLee appears to have alleged both an on-Table claim and off-Table claim. A previous ruling found that she did not prevail on her on-Table claim. The present decision addresses her off-Table claim. For the reasons explained below, she has failed to present preponderant evidence supporting her off-Table claim. Thus, her case is DISMISSED.

I. Summary of the Evidence³

A. Medical Records Before Vaccination, Including Vaccination

Ms. McLee was born on May 1, 1960. Exhibit 1 at pdf 1. She is left-hand dominant. Exhibit 3 at pdf 1. At the time of vaccination, Ms. McLee worked full time as a patient information coordinator at the University of Pittsburgh Medical Center ("UPMC") Passavant Cranberry, a job that requires frequent typing. CM/ECF 18-2 at pdf 4; Exhibit 5 at pdf 27.

On September 27, 2017, Ms. McLee visited Dr. Farrell for a pre-operative evaluation for a cataract surgery scheduled for October 6, 2017. CM/ECF 18 at pdf 38. Dr. Farrell noted no issues nor any need to take special precautions with respect to the upcoming cataract surgery. <u>Id.</u> at pdf 41. He discussed the cessation of smoking with Ms. McLee and asked for a six-month follow up. <u>Id.</u>

During her visit with Dr. Farrell on September 27, 2017, Ms. McLee received the flu vaccine. CM/ECF 20-2; Exhibit 2A at pdf 1. Here, there is a dispute regarding whether Ms. McLee received her flu vaccine in her right or left deltoid. The medical records indicate that Ms. McLee received the flu vaccine in her right deltoid. Exhibit 2A at pdf 1.⁴ However, Ms. McLee later complained of

³ The "Summary of the Evidence" is taken from the May 10, 2023 Ruling. The evidence is resummarized to present a complete decision. <u>See Cottingham v. Sec'y of Health & Hum.</u> Servs., 971 F.3d 1337, 1345 n.2 (Fed. Cir. 2020).

⁴ Ms. McLee disputes the accuracy of these records and claims she received the vaccine in her left deltoid. Exhibit 5 at pdf 32; CM/ECF 53-2 (Onset Aff.) at pdf 3. In her motion for summary judgment, Ms. McLee asserts the discrepancies "are based on PCP deception." Pet'r's Mot., filed Nov. 5, 2021, at 2. Ms. McLee reports that "a record correction was requested," though it apparently was not granted as no corrections were provided. <u>Id.</u> Ms. McLee "denies responsibility for MD's fake assessment and documentation which disregarded [her] left arm pain." <u>Id.</u>

and sought treatment for left arm pain. See, e.g., Exhibit 8 at pdf 1; Exhibit 3 at pdf 1.

B. Medical Records After Vaccination

1. Medical Records from December 9, 2017 to March 27, 2018

On December 9, 2017, approximately 10 weeks after receiving the flu vaccine, Ms. McLee sought treatment at MedExpress Ross Township Urgent Care for left shoulder pain. CM/ECF 18-2 at pdf 4. The doctor reported limited flexion and extension in Ms. McLee's left shoulder due to pain. <u>Id.</u> Ms. McLee denied any injury and was diagnosed with an unspecified sprain of her left shoulder joint and prescribed prednisone. <u>Id.</u> at pdf 6. The medical records from this visit indicate that Ms. McLee was experiencing "L shoulder pain x 1 month" that was aggravated due to frequent typing at work. <u>Id.</u> at pdf 4. This history implies that Ms. McLee's shoulder pain began around November 9, 2017.

On December 13, 2017, Ms. McLee visited the UPMC emergency room. Exhibit 3 at pdf 1; CM/ECF 17 at pdf 14. The medical records indicate her primary complaint was a "one month history of left arm pain accompanied by intermittent episodes of numbness and tingling." Exhibit 3 at pdf 1. This history suggests the onset of pain was around November 13, 2017. Ms. McLee also stated that she had "perceived weakness in her left hand." Id. She denied any specific injury and stated that her pain extended "from her trapezius along the lateral side of her arm," with the pain being exacerbated by any type of movement. Id. Ms. McLee stated that she began working out with a trainer starting approximately six weeks prior but had not done any exercises that caused the shoulder injury. Id. She denied any trauma besides being on the computer during work. Id. at pdf 4. She described her left arm as feeling heavy and felt a shooting pain when her left shoulder blade, dorsal aspect of the upper left arm, and antiecubitis areas were pressed. Id. At the time of this visit, Ms. McLee had almost finished the steroids she was prescribed on December 9, 2017, and noted that even a high dose of the steroid did not help her pain. <u>Id.</u> at pdf 1. Upon physical examination, Ms. McLee had tenderness in her left trapezius on palpation and a slightly weaker grip on the left side. Id. at pdf 2. Additionally, Ms. McLee experienced a significant increase in pain on her left side while doing a shoulder shrug. Id. She was diagnosed with intractable left cervical radicular pain and transferred to UPMC Passavant McCandless for further evaluation and treatment. Id. at pdf 3.

Later that same day, Ms. McLee was seen by another physician at the UPMC, Dr. Amit, for a spine consultation. Exhibit 3 at pdf 7. The medical records state that she had progressive weakness and pain in the left upper extremity which started in the left scapula, went across the neck and over both biceps and triceps, with numbness in all 5 fingers on the left "over the last 1½ months." Id. This history implies that the onset of Ms. McLee's pain would have been around late October 2017. Ms. McLee denied symptoms in her right upper extremity. Id. Upon musculoskeletal examination, Ms. McLee could not abduct more than 15 degrees on the left upper extremity. Id. at pdf 8. Because Ms. McLee's condition had not improved with oral prednisone or IV solumedrol, Dr. Amit prescribed Robaxin for pain control. Id. at pdf 10.

On December 14, 2017, Ms. McLee reported back to the University of Pittsburgh Medical Center with worsening pain with range of motion of the left arm. Exhibit 3 at pdf 25. Ms. McLee was tender to palpation of the left trapezius area and had occasional tingling and numbness in her left arm. <u>Id.</u>

The next day, on December 15, 2017, Ms. McLee was ordered to undergo a brain MRI exam with and without contrast. Exhibit 3 at pdf 13. The purpose of the exam was to rule out a stroke. <u>Id.</u> The impression was no acute intracranial abnormality, meaning no acute stroke. <u>Id.</u> That same day, Ms. McLee told Dr. Shtrahman, a neurologist, that she was feeling better. <u>Id.</u> at pdf 23. Dr. Shtrahman diagnosed Ms. McLee with "[l]eft upper extremity pain and 'weakness'" and noted that the workup thus far had been unremarkable. <u>Id.</u> For next steps, Dr. Shtrahman recommended an EMG and nerve conduction studies. <u>Id.</u> Ms. McLee was stable for discharge. <u>Id.</u>

Ms. McLee saw Dr. Farrell again on January 3, 2018. Exhibit 5 at pdf 25. The medical records show that she informed him that weakness in her left arm "ha[d] been developing slowly since October" of 2017. Id. At the time of this visit, Ms. McLee had no symptoms on her right side or neck. Id. Dr. Farrell noted that there was no acute trauma or injury. Id. Ms. McLee's left side presented with tenderness in the left trapezius ridge and her range of motion on the left shoulder was restricted. Id. Dr. Farrell indicated that Ms. McLee had impingement syndrome of the left shoulder. Id. He noted that her grip strength on the left side was maybe just a little weaker, especially considering that Ms. McLee is left-handed. Id. Dr. Farrell referred her to an orthopedist to give her a prescription for physical therapy. Id.

On January 16, 2018, Ms. McLee visited orthopedist Dr. Gause. CM/ECF 18-2 at pdf 18. Dr. Gause's notes state that Ms. McLee is right-hand dominant⁵ and presented for evaluation of the left shoulder. <u>Id.</u> The records indicate that Ms. McLee reported that the onset of her pain "2 months ago on 11/20/17 after receiving a flu shot." <u>Id.</u> The records further state that her pain was "localized somewhat diffusely about her neck traveling into the left trapezius and anterolateral aspect of her left shoulder." <u>Id.</u> Ms. McLee reported a "constant achy pain" as well as "numbness in her fingers" and "some decreased range of motion and weakness." Id.

On January 24, 2018, Ms. McLee had her first visit with physical therapist Matthew Sennott. CM/ECF 20-8 at pdf 7. The date of onset was reported as September 18, 2017. <u>Id.</u> at pdf 12. Ms. McLee stated that she had "increased muscle pain in her l[eft] shoulder following a flu shot in September 2017." <u>Id.</u> The pain, as Ms. McLee described, progressed like a toothache. <u>Id.</u> Mr. Sennott noted that Ms. McLee is left-hand dominant and worked a desk job that required a lot of time typing and writing. <u>Id.</u> The next day, on January 25, 2018, Ms. McLee had an MRI performed on her left shoulder. <u>Id.</u> at pdf 29. There were no significant derangements in the left shoulder. CM/ECF 28 at pdf 35.

Ms. McLee saw Dr. Esman on January 29, 2018, for left upper extremity pain. CM/ECF 18-2 at pdf 19-20. Dr. Esman noted that Ms. McLee was left-hand dominant and presented with a four-month history of pain in her left upper arm, along with tingling and numbness in her forearm and fingertips. <u>Id.</u> This history suggests that the onset of pain began approximately on September 29, 2017. Ms. McLee also believed the problem started after getting her flu shot. <u>Id.</u> Dr. Esman found that Ms. McLee had diffuse mild weakness throughout the left upper extremity. <u>Id.</u> Nerve studies were performed, and the nerve conduction portion was normal and showed no evidence of carpal tunnel syndrome or ulnar neuropathy or any evidence of impairment of sensory amplitudes as would be seen in a brachial plexus lesion. <u>Id.</u>

On February 2, 2018, Ms. McLee saw Dr. Gause again. CM/ECF 18-2 at pdf 28-29. Dr. Gause's notes state that Ms. McLee was bothered by diffuse neck pain traveling into her left shoulder and arm. <u>Id.</u> at pdf 21. Dr. Gause concluded that at this point, he could not find an etiology for her symptoms and recommended

⁵ This appears to be incorrect because the medical records consistently indicate that Ms. McLee is left-hand dominant. See, e.g., CM/ECF 18-2 at pdf 19; CM/ECF 20-8 at pdf 7; Exhibit 3 at pdf 1; Exhibit 5 at pdf 25, 27.

that Ms. McLee follow up with her primary care physician. <u>Id.</u> at pdf 29. Additionally, that same day, Ms. McLee had physical therapy with Matthew Sennott. CM/ECF 20-8 at pdf 4. Mr. Sennott noted that Ms. McLee had continued soreness in her left shoulder, which she said was so bad that it was numbing at times. <u>Id.</u> Ms. McLee also said that typing all day at work had increased her symptoms. <u>Id.</u> She was subsequently discharged from physical therapy on March 9, 2018, likely because she was too busy working to attend the sessions. CM/ECF 20-8 at pdf 17; Exhibit 8 at pdf 1.

On a follow up visit to Dr. Farrell on February 6, 2018, Ms. McLee described her left shoulder pain as beginning in mid-September 2017. Exhibit 5 at pdf 27. He noted that her pain continued in the same place and severity as the last time he saw her. <u>Id.</u> Ms. McLee explained that her sleep was disturbed due to the pain so she could not sleep on her back, and instead needed to sleep right laterally recumbent. <u>Id.</u> However, the pain was not deep aching and Ms. McLee was not noticing motor weakness. <u>Id.</u> He noted that she is left-handed and was working as a clerical person checking inpatient stay at UPMC Passavant Cranberry and had not missed work due to the pain. <u>Id.</u> Dr. Farrell explained that her range of motion of the shoulder was limited in elevation extension, and that it would be helpful if Ms. McLee could tolerate nerve conduction studies. <u>Id.</u> He suggested a referral to Dr. Cheryl Bernstein for neurology and pain medicine and prescribed Cymbalta. <u>Id.</u> at pdf 27-28.

On March 27, 2018, Ms. McLee visited UPMC Pain Medicine and saw Dr. Bernstein. CM/ECF 28 at pdf 40. Ms. McLee's chief complaints were arm and hand pain, with an onset date reported as September 17, 2017. <u>Id.</u> at pdf 40, 52. Dr. Bernstein diagnosed Ms. McLee with chronic pain syndrome and found that there were no significant internal derangements in the left shoulder. <u>Id.</u> at pdf 40, 45. Ms. McLee was referred to an occupational therapist and a physical therapist, as well as referred for a psychological evaluation for her chronic pain syndrome. <u>Id.</u> at pdf 47.

2. <u>Medical Records from April 6, 2018 to November 13, 2018</u>

Ms. McLee had a follow up appointment with Dr. Farrell on April 6, 2018, for chronic pain from the anterior shoulder distal to the hand with paresthesia without diagnosis. Exhibit 5 at pdf 28-29. Dr. Farrell noted that there had been no change in pain intensity, character, or location, or pain at new sites since he last saw Ms. McLee. <u>Id.</u> Additionally, Ms. McLee's range of motion of the shoulder

was limited. <u>Id.</u> He referred her for another orthopedic opinion at Western Pennsylvania Hand and Upper Extremity Center. <u>Id.</u>

On April 27, 2018, Ms. McLee was evaluated by Dr. Balk at the Hand and Upper Extremity Center. Exhibit 8 at pdf 1. Ms. McLee's primary complaints were of left upper arm pain and stiffness and left-hand numbness, which she attributed to a flu vaccine from September 2017. Id. She expressed that she had a constant throbbing pain in her left upper arm that sometimes radiated to her neck. Id. Dr. Balk noted that Ms. McLee was prescribed physical therapy but could not attend because of a busy work schedule. Id. He recommended more physical therapy as well as a cortisone injection, which Ms. McLee declined. Id. at pdf 3. Additionally, Dr. Balk expressed the importance of a nerve conduction study for Ms. McLee's complaints of hand numbness. Id.

On May 8, 2018, Ms. McLee again visited Dr. Bernstein for arm and hand pain. CM/ECF 28 at pdf 30. Ms. McLee was scheduled for a repeat EMG/NCS of the left upper extremity because she could not tolerate the EMG the first time. <u>Id.</u> Ms. McLee had not had much relief from her pain, mostly because she could not attend physical therapy appointments due to her work schedule. <u>Id.</u> On physical examination, Ms. McLee could not actively get past 45 degrees abduction on the left side. <u>Id.</u> at pdf 34. Dr. Bernstein suggested that Ms. McLee consider a shoulder injection, suprascapular nerve block, to improve her range of motion without pain. Id. at pdf 36.

Ms. McLee revisited Matthew Sennott on May 10, 2018, for physical therapy for chronic left shoulder pain. CM/ECF 20-9 at pdf 23. He noted that she was experiencing difficulty with activities of daily living, including active shoulder motion, dressing, and driving. <u>Id.</u> at pdf 28. Additionally, Ms. McLee had been having trouble with work duties, including keyboarding, writing, and using the phone. <u>Id.</u> On May 15, 2018, she returned to physical therapy and reported that she had continued pain and was having trouble sleeping because she was unable to find a comfortable position. <u>Id.</u> Ms. McLee did not tolerate the session well, and reported increased pain with any motion at or about 90 degrees. <u>Id.</u> at pdf 42-43. Ms. McLee had another session with Mr. Sennott on May 17, 2018, and reported continued soreness and intermittently completing her home exercise program. <u>Id.</u> at pdf 48. She had good tolerance to this session and completed progressions with minimal soreness. <u>Id.</u> She reported for a final session on May 24, 2018, and was subsequently discharged with a recommendation for an independent home program. <u>Id.</u> at pdf 54-56.

On August 13, 2018, Ms. McLee visited the emergency room due to abdominal pain, nausea, and diarrhea. CM/ECF 17 at pdf 7. Additionally, Ms. McLee noted she had chronic left arm pain for the last year since her flu shot but had seen a specialist and was taking ibuprofen to manage the pain. Id. The doctor also noted blood in her urine, which he treated as a urinary tract infection and recommended she see a urologist in two weeks if the bleeding in her urine did not subside. Id. at pdf 8. Ms. McLee was formally diagnosed with abdominal pain, hematuria with concern for urinary tract infection, and elevated systolic blood pressure without a history of hypertension. Id.

The next day, on August 14, 2018, Ms. McLee had a follow up visit with Dr. Farrell. Exhibit 5 at pdf 29. He explained to her that her pain seemed like a chronic problem and that they needed to work to try to suppress her pain. <u>Id.</u> at pdf 30. The medical records reflect that Ms. McLee thought her left arm was getting weaker. <u>Id.</u> She noted that she had exercises that she learned from physical therapy, but Dr. Farrell mentioned that he did not think she was doing the exercises regularly. <u>Id.</u> He raised her dosage of Cymbalta and recommended she revisit Dr. Bernstein to discuss the possibility of a nerve block. <u>Id.</u>

On November 23, 2018, Ms. McLee returned to Dr. Bernstein for continued left arm pain. CM/ECF 28 at pdf 22, 26. She reported pain in her "left neck, shoulder, and arm," and reported that her "fingers are always numb" and "bicep is a constant toothache." <u>Id.</u> at pdf 23. Ms. McLee was to undergo a repeat EMG, but she stated that she did not want to do so despite having continued numbness and tingling. <u>Id.</u> at pdf 22, 26. Further, the records reflect that Ms. McLee did not believe the Cymbalta was improving her pain. <u>Id.</u> The attending noted neuropathic pain and recommended that Ms. McLee increase her dosage of Cymbalta and consider nortriptyline. <u>Id.</u> at pdf 26.

3. Medical Records from February 19, 2019 to April 2, 2021

Ms. McLee reported for a radiology consultation on February 19, 2019, for congestion, productive cough, and body aches for ten days. CM/ECF 28 at pdf 8. She received a chest x-ray and was diagnosed with bronchitis. <u>Id.</u>; CM/ECF 18-2 at pdf 3. She was prescribed benzonatate, prednisone, ventolin, and an inhaler. CM/ECF 18-2 at pdf 3.

On August 13, 2019, Ms. McLee went to MedExpress because of swelling in her right shoulder after a flu shot two years ago. CM/ECF 18-2 at pdf 10. She reported tingling and numbness, and stated she had been careful with it since. She

also reported pain around the scapula. <u>Id.</u> She was diagnosed with a sprain of the ligaments of the thoracic spine and was prescribed prednisone and cyclobenzaprine. <u>Id.</u> at pdf 11.

No other relevant medical records have been filed.⁶

C. Affidavits⁷

Ms. McLee completed an onset affidavit, which was initially filed on March 30, 2022. CM/ECF 53-2 (Onset Aff.). Ms. McLee claims that her left shoulder pain began immediately "upon needle stick" and describes the pain as "shocking, continuous, [and] expansive." Id. at pdf 2. She states that the part of her shoulder that was affected was "the injection site area and beyond." Id. She claims that she could not lift her arm above her shoulder and felt like her arm was paralyzed. Id. Ms. McLee claims that during her appointment on September 27, 2017, she "immediately" informed the nurse who administered the vaccine, Kala Cinker, that she was experiencing shoulder pain. Id. Additionally, Ms. McLee states that she had difficulty sleeping later that night due to constant repositioning in her bed, which she needed help doing. Id. She represents that her full left shoulder area was affected, and she could not lift her arm above her shoulder. Id.

Ms. McLee also disputes the accuracy of certain medical records which state the onset of her pain. The medical records from December 9, 2017 state that Ms. McLee had been experiencing left arm pain for one month, and additional medical records from December 13, 2017 state that Ms. McLee had been experiencing left arm pain for the past one-and-a-half months; however, Ms. McLee denies this and maintains that her entire arm was in pain since September 27, 2017. <u>Id.</u> at pdf 3-4.

⁶ Ms. McLee filed additional materials in CM/ECF 42, including records regarding a cataract surgery on October 6, 2017; COVID vaccination records; records from visits to the UPP Department of Dermatology and Specialists in Plastic Surgery of Pittsburgh regarding a mass in Ms. McLee's upper right arm; and records from UPMC Heart and Vascular Institute. However, CM/ECF 42 was stricken from the record because it contained multiple filings which were not properly labeled as exhibits. Ms. McLee was ordered to individually refile documents in this filing with clear exhibit headings, but did not do so. See Order, issued Aug. 19, 2022.

⁷ Affidavits from Ms. McLee's children, Hannah Avva and Bradley McLee Jr., were filed on March 30, 2022 with CM/ECF 42, but were never resubmitted after this filing was stricken from the record. Bradley McLee Jr. stated that he spoke to Ms. McLee the day of her September 27, 2017 vaccination, and Hannah Avva stated that she spoke with Ms. McLee a few days after. Both stated that she told them her pain began immediately.

Similarly, medical records from January 3, 2018, state that Ms. McLee's pain had been developing since October 2017, which she denies saying. <u>Id.</u> Finally, Ms. McLee disputes the medical record from January 16, 2018, which states that she had been experiencing left arm pain since November 20, 2017. Id. at pdf 5.

In an affidavit by Ms. McLee's husband, Bradley McLee Sr., submitted February 3, 2023, Mr. McLee alleges that the medical records are "erroneous" due to "mistakes or lies" on the part of healthcare providers. CM/ECF 53-1 at pdf 2. Specifically, Mr. McLee states that the records showed the "wrong arm", and that "[r]eports of non-injury, right arm, later onset of pain, PCP notes, etc. are preposterous." <u>Id.</u> at pdf 3. He also describes Ms. McLee's "pain, loss of motion, [and] weariness." Id.

II. Procedural History

The procedural history of Ms. McLee's case is detailed in the ruling dismissing the Table claim. <u>See Ruling</u>, issued May 10, 2023, 2023 WL 3750615. Thus, this history is provided summarily.

Ms. McLee first filed her petition on September 28, 2020, alleging "injuries, including Guillain Barre Syndrome" and a shoulder injury related to vaccine administration ("SIRVA"). On March 3, 2021, Ms. McLee filed an amended petition, again alleging "injuries, including Guillain Barre Syndrome" and "SIRVA."⁸

On November 5, 2021, Ms. McLee moved for summary judgment, requesting compensation for her alleged SIRVA. The Secretary opposed Ms. McLee's motion, arguing that Ms. McLee had neither proven SIRVA nor that her alleged injury was caused-in-fact by the vaccination. Resp't's Rep., filed Nov. 19, 2021 at 17. The Secretary also moved to dismiss the case, raising, *inter alia*, an issue of statute of limitations. <u>Id.</u> at 14 n.10. Ms. McLee did not file a response to the Secretary's motion. The undersigned issued an order instructing both parties to file a status report on whether a hearing would be appropriate. Order, issued July 26, 2022. The Secretary stated that a hearing was not appropriate in this case. Resp't's Status Rep., filed Sept. 1, 2022. Ms. McLee did not submit a filing regarding her position on whether a hearing was appropriate.

⁸ Although Ms. McLee alleged she suffered from Guillain-Barré syndrome, medical records do not persuasively show that she suffered from Guillain-Barré syndrome.

During a status conference, Ms. McLee questioned the accuracy of the medical records and mentioned that she received the COVID-19 vaccine. Subsequently, Ms. McLee was ordered to complete an onset affidavit and to file her COVID-19 vaccination record by February 25, 2022. Order, issued Jan. 26, 2022. After being granted an extension of time, Ms. McLee filed the additional requested medical records on March 30, 2022. CM/ECF 42. This filing was later stricken for failure to appropriately label the records as exhibits. See Order, issued Apr. 11, 2022; Pet'r's Exhibit List, filed May 9, 2022; Order, issued Aug. 19, 2022. Ms. McLee was ordered to refile the non-duplicative exhibits from CM/ECF 42 individually and instructed that she may file an affidavit from her husband describing his observations of her vaccination by November 17, 2022. Id.

Ms. McLee did not file an affidavit by the deadline, nor did she refile the exhibits specified in the August 19, 2022 order. It appeared that Ms. McLee had attempted to communicate with a person whose employment within the Office of Special Masters had ended, and so the undersigned, sua sponte, extended the deadline for the exhibits and affidavit to January 26, 2023. Order, issued Dec. 28, 2022. Ms. McLee contacted chambers and the undersigned's law clerk the week of the deadline to inform of an intent to file these materials, but did not file anything. Ms. McLee also did not file a status report detailing why she failed to file these materials. The undersigned, sua sponte, extended the deadline to February 3, 2023, reminding Ms. McLee to file through the CM/ECF system. Order, issued Jan. 27, 2023. On February 3, 2023, Ms. McLee filed an affidavit from her husband, and refiled her affidavit about the onset of her symptoms. CM/ECF 53-1, 53-2. She did not refile the non-duplicative materials from CM/ECF 42.

The undersigned issued a ruling dismissing Ms. McLee's on-Table claim for unpersuasive evidence. Ruling, issued May 10, 2023, 2023 WL 3750615. The undersigned determined that Ms. McLee established one element of a SIRVA claim---that she had no history of shoulder pain prior to vaccination. However, Ms. McLee's proof on other elements was lacking. For instance, the records created closest in time to Ms. McLee's vaccination did not support her claim that her shoulder pain began within 48 hours. Instead, the onset was in early November 2017. Additionally, although Ms. McLee recalled receiving the vaccine in her left shoulder, the record supported a finding that she received the vaccine in her right shoulder. Finally, even if the vaccine had been administered in Ms. McLee's left shoulder, her pain and reduced range of motion were not limited to this shoulder; the medical records and Ms. McLee's own statements consistently described her pain as extending to her hand, fingers, and neck. Thus, Ms. McLee's injury did not meet the SIRVA criteria, and her on-Table SIRVA claim was dismissed.

However, although Ms. McLee predominantly referenced SIRVA in her filings, she might prevail upon other claims. The undersigned determined that Ms. McLee had alleged off-Table shoulder injuries, and could pursue an off-Table claim. Ms. McLee was ordered to file a status report within 60 days (by July 12, 2023) through CM/ECF confirming that she had retained an expert. The undersigned stated that, if Ms. McLee did not comply with this order, her off-Table claim would be dismissed.

Ms. McLee has not filed anything since the ruling was issued. Ms. McLee appears to have attempted to email a "complaint" about the undersigned and an "appeal of his decision" to the Secretary's counsel on June 26, 2023. However, no documents were attached to this email. The Secretary's counsel informed Ms. McLee that there were no attachments and provided instructions on how to submit pro se filings, but Ms. McLee took no further action. Ms. McLee's husband contacted chambers on August 11, 2023 seeking additional information on the procedures for a complaint and review. Neither communication indicated an intent to file additional evidence or retain an expert.

III. Analysis

Ms. McLee's case raises two questions. First, whether her case should be resolved presently? And, second, if so, how does the evidence preponderate? These are taken up in turn.

A. Now is an Appropriate Time to Resolve the Case

With some assistance from her husband, who is not an attorney, Ms. McLee has represented herself competently. She mostly complied with orders to submit material through the CM/ECF system.

Ms. McLee has not responded to the May 10, 2023 ruling, requiring her to submit a status report within 60 days (or by July 12, 2023) regarding an intention to submit an expert report. As discussed below, Ms. McLee seems unlikely to obtain a report from an expert that would assist her. Thus, extending more time on a sua sponte basis would appear to be only delaying an inevitable conclusion. In addition, the informal communication from Ms. McLee's husband suggests that Ms. McLee wants to appeal the May 10, 2023 ruling. Under these circumstances, Ms. McLee's off-Table claim can be adjudicated immediately.⁹

⁹ A petitioner's failure to comply with orders can be the basis for a dismissal for failure to prosecute. <u>See Tsekouras v. Sec'y of Health & Human Servs.</u>, 26 Cl. Ct. 439 (1992), <u>aff'd</u>, 991

B. The Evidence Does Not Preponderate in Petitioner's Favor

As explained to Ms. McLee in the May 10, 2023 ruling, an off-Table claim requires a petitioner to present "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). The source of this evidence must be "medical records" or "medical opinion." 42 U.S.C. § 300aa–13(a)(1).

Here, Ms. McLee has not presented reliable evidence in the form of medical record or medical opinion that could carry her burden of proof on these elements.¹⁰ This lack of evidence justifies the dismissal.

In the undersigned's "accumulated expertise," Ms. McLee seems unlikely to be able to present a minimally persuasive statement from an expert supporting her claim. See Whitecotton v. Sec'y of Health & Hum. Servs., 81 F.3d 1099, 1104 (Fed. Cir. 1996). The May 10, 2023 ruling found that the onset of Ms. McLee's shoulder pain was approximately six weeks after her flu vaccine. A passage of this much time makes the flu vaccine unlikely to be causal. See Greene v. Sec'y of Health & Hum. Servs., 146 Fed. Cl. 655, 667 (2020) (determining that the special master was not arbitrary in determining that 41 days was not a medically appropriate interval for brachial neuritis), aff'd, 841 F. App'x 195 (Fed. Cir. 2020).

IV. Conclusion

It is clear that Ms. McLee has a loving and supportive family who want the best for her health and wellbeing. However, Ms. McLee has not shown that the Vaccine Program can compensate her, as she has not satisfied the elements for an on-Table SIRVA claim, and she has not presented sufficient evidence for her off-Table claim. Thus, this case is dismissed for lack of persuasive evidence.

F.2d 810 (Fed. Cir. 1993) (table). However, Ms. McLee's off-Table claim is being resolved due to a lack of persuasive evidence, not due to a procedural misstep.

¹⁰ Although Ms. McLee asserts that the flu vaccine caused her shoulder problems, a special master cannot award compensation based upon "the claims of a petitioner alone." 42 U.S.C. § 300aa–13(a)(1).

The Clerk's Office is instructed to dismiss this case and to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline for any such submission, is available through the Vaccine Rules posted on the website for the Court of Federal Claims.

IT IS SO ORDERED.

S/Christian J. Moran Christian J. Moran Special Master